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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,018	07/07/2003	Ursula-Henrike Wienhues	2923-543	8627

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,018	WIENHUES ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *5,8,13 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,9-12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/776,188.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10;11;12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *PTO-90C and Notice to Comply*.

DETAILED ACTION

Status of the Claims

1. Claims 1-24 are currently pending and under consideration.

Election/Restrictions

2. Applicant's election of Group I (claims 1-15 and 19-22) in the reply filed on February 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 16-18 and 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 10, 2006.

4. Applicant's election of HIV as the species of pathogenic organism, digoxigenin as the species of hapten, BSA as the species of carrier, and SEQ ID NO. 5 as the species of "P" or peptide epitope in the reply filed on February 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. Claims 5, 8, 13, 15, and 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 10, 2006.

6. Claims 1-4, 6-7, 9-12, and 14 are currently under consideration.

Drawings

7. The drawings/figures (Figure 1) are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 CFR §1.58(a) and §1.83(a). Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 CFR §§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any figures/drawings which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (e.g. as SEQ ID Nos.) and should further amend the specification accordingly to reflect the replacement of the drawing/figure by the appropriate SEQ ID No(s).

Appropriate correction is required.

Specification

8. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables

having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

9. The disclosure is objected to because of the following: SEQ ID Nos. are not identified regarding the sequences listed throughout the specification. For example, pages 18-19 and 35-37 of the Specification list several sequences, however, SEQ ID Nos. for each specific sequence are not provided. Furthermore, Tables 2a, 2b, 2c, 2d, 3a, 3b, 3c, 3d do not provide SEQ ID Nos.

MPEP § 2422 and 37 CFR 1.821 2(d) state that where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Appropriate correction is required.

Please also refer to enclosed PTO-90C and Notice to Comply with a SHORTENED statutory period of ONE month.

Claim Interpretation

10. The presently claimed invention is directed to:

A method comprising the following steps:

a. incubating a liquid sample, a solid phase, a first antigen with a marker group, and a second antigen together, and

b. detecting the antibody directly or indirectly via detection of the marker group wherein one of the antigens has a formula of $(P\text{-})_nT(\text{-}L)_m$ or $(T(\text{-}P\text{-}L_m)_n$ wherein T = carrier, P = peptide with an epitope, L = marker group, n = 2-40, and m = 1-10.

The limitation that the second antigen binds to the solid phase is considered to be a functional limitation only. In addition, the limitation that the second antigen is bound to the antibody and the antibody is bound to the first antigen is considered to be a functional limitation only. Furthermore, the limitation that the L = a group which binds to the solid phase is considered to be a functional limitation only.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 9-11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashida et al., Diagnosis of HIV-1 Infection by Detection of Antibody IgG to HIV-1 Urine with Ultrasensitive Enzyme Immunoassay (Immune Complex Transfer Enzyme Immunoassay) Using Recombinant Proteins as Antigens, Journal of Clinical Laboratory Analysis, 8(4): 237-246, 1994.

For present claim 1 method step a), Hashida et al. teach incubating a urine sample (e.g. liquid sample), a solid phase, a first antigen for the anti-HIV-1 IgG (e.g. antibody) covalently

linked to an enzyme (e.g. marker group), a second antigen for the anti-HIV-1 IgG covalently linked to DNP which binds to anti-DNP antibody bound to the solid phase to form a complex which is schematically depicted in Figure 1, and also a third antigen may be utilized (please refer to Figure 1, Abstract section, and pages 237-243).

For present claim 1 method step b), Hashida et al. teach detecting the antibody bound to the antigens via fluorescence or color development (please refer to Materials and Methods section, Figures 1-13, and pages 239-243).

For present claim 1 method step b) and claims 2-4, Hashida et al. teach the antigen being conjugated (e.g. covalently bound) to both BSA (e.g. carrier) and enzyme labels (e.g. marker group) via various thiol and maleimide groups and either utilizing RT as antigen alone (e.g. multiple epitopes and multiple copies of the same amino acid groups and the first and second antigens are the identical amino acid sequence) or utilizing RT, p17, and p24 (e.g. multiple epitopes and multiple copies of the same amino acid groups) (e.g. $T(\text{-}P\text{-}L_m)_n$ or $(P\text{-})_nT(\text{-}L)_m$; please refer to Materials and Methods section, Figures 1-13, and pages 239-243).

For present claims 9-11, Hashida et al. teach that BSA or bovine serum albumin is coupled to the antigens (e.g. carrier; please refer to Material and Methods section).

For present claim 14, Hashida et al. teach that p17 (e.g. 131 amino acids), p24 (e.g. 231 amino acids), and RT (e.g. 1000 amino acids) are utilized as antigens and are produced via recombinant techniques (e.g. up to 1000 amino acids; please refer to Materials and Methods section).

Therefore, one of skill in the art would have anticipated the presently claimed invention in view of the teachings of Hashida et al.***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-4, 9-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashida et al., Diagnosis of HIV-1 Infection by Detection of Antibody IgG to HIV-1 Urine with Ultrasensitive Enzyme Immunoassay (Immune Complex Transfer Enzyme Immunoassay) Using Recombinant Proteins as Antigens, Journal of Clinical Laboratory Analysis, 8(4): 237-246, 1994 and Formoso et al. WO 90/07119 published June 28, 1990.

For present claim 1 method step a), Hashida et al. teach incubating a urine sample (e.g. liquid sample), a solid phase, a first antigen for the anti-HIV-1 IgG (e.g. antibody) covalently linked to an enzyme (e.g. marker group), a second antigen for the anti-HIV-1 IgG covalently linked to DNP which binds to anti-DNP antibody bound to the solid phase to form a complex which is schematically depicted in Figure 1, and also a third antigen may be utilized (please refer to Figure 1, Abstract section, and pages 237-243).

For present claim 1 method step b), Hashida et al. teach detecting the antibody bound to the antigens via fluorescence or color development (please refer to Materials and Methods section, Figures 1-13, and pages 239-243).

For present claim 1 method step b) and claims 2-4, Hashida et al. teach the antigen being conjugated (e.g. covalently bound) to both BSA (e.g. carrier) and enzyme labels (e.g. marker group) via various thiol and maleimide groups and either utilizing RT as antigen alone (e.g. multiple epitopes and multiple copies of the same amino acid groups and the first and second

antigens are the identical amino acid sequence) or utilizing RT, p17, and p24 (e.g. multiple epitopes and multiple copies of the same amino acid groups) (e.g. $T(-P-L_m)_n$ or $(P-)_nT(-L)_m$; please refer to Materials and Methods section, Figures 1-13, and pages 239-243).

For present claims 9-11, Hashida et al. teach that BSA or bovine serum albumin is coupled to the antigens (e.g. carrier; please refer to Material and Methods section).

For present claim 14, Hashida et al. teach that p17 (e.g. 131 amino acids), p24 (e.g. 231 amino acids), and RT (e.g. 1000 amino acids) are utilized as antigens and are produced via recombinant techniques (e.g. up to 1000 amino acids; please refer to Materials and Methods section).

However, Hashida et al. do not teach peptide sequences of 6-50 amino acids.

For present claim 12, Formoso et al. teach synthetic peptides conjugated through the C-terminus to a carrier protein which are typically about 5 to about 22 amino acids in length and preferably 11-20 amino acids or 15-17 amino acids in length (e.g. sequences of 6 to 50 amino acids; please refer to page 3, lines 22-32, page 4, lines 33-35, page 9, lines 24-36).

For the present elected species of SEQ ID No: 5, Formoso et al. teach peptides of HIV-1 gp41 with the amino acid sequence of 1-15 of present SEQ ID No: 5 (please refer to claims 2 and 11).

In addition, Formoso et al. teach that the carrier protein is preferably BSA, the peptides can be utilized in determining the presence of HIV-1 or HIV-2 antibodies in fluid samples, and that multiple peptides can be utilized in the ELISA, EIA, or RIA assays to determine the presence of HIV antibodies (please refer to pages 3-4 Summary of the Invention section and pages 8-17 Description of the Specific Embodiments section).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for an ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al.

One having ordinary skill in the art would have been motivated to do this because Formoso et al. teach that synthetic peptides allow standardized antigen production, avoidance of nonspecificity resulting from contaminating proteins of *E. coli* (e.g. utilized by Hashida et al. for antigen production), and reduce time of incorporating new antigens necessitated by mutation of HIV peptides which will improve tests for HIV specific antibodies (please refer to page 3, lines 7-20 of Formoso et al.). In addition, Hashida et al. teach that mutation of HIV proteins especially after prolonged drug treatment is a concern for the specificity of HIV antibody assays (please refer to page 244 of Hashida et al.).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the method for an ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al. because Formoso et al. have shown the success of the screening and identification of antibodies using optimally immunoreactive peptides (please refer to page 11, lines 19-36 and page 12, lines 1-6 and Examples 1-20). In addition, the results of Hashida et al. show that the assay is more sensitive and specific than regular ELISA assays (please refer to Figures 1-16, particularly Figures 10 and 12-13; page 241-244 Diagnosis of HIV-1 Infection with Urine Samples section).

Therefore, the modification of the method for an ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al. render the instant claims prima facie obvious.

15. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashida et al., Diagnosis of HIV-1 Infection by Detection of Antibody IgG to HIV-1 Urine with Ultrasensitive Enzyme Immunoassay (Immune Complex Transfer Enzyme Immunoassay) Using Recombinant Proteins as Antigens, Journal of Clinical Laboratory Analysis, 8(4): 237-246, 1994 and Formoso et al. WO 90/07119 published June 28, 1990 as applied to claims 1-4, 9-12, and 14 above, and further in view of Watts et al. U.S. Patent 5,437,983 filed February 1, 1993.

Hashida et al. teaches a method comprising incubating a urine sample, a solid phase, a first antigen covalently linked to an enzyme, a second antigen bound to the solid phase to form a complex and detecting the antibody bound to the antigens via fluorescence or color development. In addition, Hashida et al. teach the antigen being conjugated to both BSA and enzyme labels and either utilizing RT as antigen alone or utilizing RT (e.g. 1000 amino acids), p17 (e.g. 131 amino acids), and p24 (e.g. 231 amino acids) as antigens. Please refer to pages 237-243 of Hashida et al. Furthermore, Formoso et al. teach synthetic peptides conjugated through the C-terminus to a carrier protein which are typically about 5 to about 22 amino acids in length (please refer to page 3, lines 22-32, page 4, lines 33-35, page 9, lines 24-36).

However, Hashida et al. or Formoso et al. do not teach the hapten of digoxigenin and utilized to detect (via anti-digoxigenin antibody) binding.

For present claims 6-7, Watts et al. teach digoxigenin (e.g. cardiotonic glycosides) and antidigoxigenin antibody in binding assays with analytes and sbp or specific binding pairs and detecting signals (please refer to column 2, lines 1-18; column 3, lines 3-52; column 4, lines 15-35; column 5, lines 1-4; and Examples).

In addition, Watts et al. teach binding of sbps including antigens to labels to produce a signal producing system, utilizing beads as solid supports, performing the assay in a liquid medium, utilizing BSA, and screening for HIV related antibodies (please refer to column 4, lines 15-29; column 6, lines 41-67; column 7, lines 1-25, column 8, lines 9-51; column 9, lines 3-41; column 10, lines 22-31; column 11, lines 11-63).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al. with the digoxigenin and anti-digoxigenin detection system taught by Watts et al.

One having ordinary skill in the art would have been motivated to do this because Watts et al. teach that various detection and labeling systems can be utilized including enzymatic, radioactive, and fluorimetric wherein one type of detection and labeling systems use is the digoxigenin and anti-digoxigenin detection system (please refer to column 1, lines 21-28). Moreover, Formoso et al. and Hashida et al. both teach that various methods of detection and labeling can be utilized in antigen-antibody binding assays and the type of detection and labeling would be a choice of experimental design (Formoso: please refer to page 17, lines 6-9; Hashida: please refer to Figures 1-16).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al. with the digoxigenin and anti-digoxigenin detection system taught by Watts et al. because Watts et al. have shown the success of using the detection and labeling systems of digoxigenin and anti-digoxigenin detection system (col. 17, lines 17-47).

Therefore, the modification of the ultrasensitive enzyme immunoassay taught by Hashida et al. with the shorter synthetic peptides taught by Formoso et al. with the digoxigenin and anti-digoxigenin detection system taught by Watts et al. render the instant claims prima facie obvious.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-12, and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-12, and 14 of U.S. Patent No. 6,613,530 B1 (Wienhues et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

For the preamble of present claim 1, Wienhues et al. claim a method of detecting an antibody against HIV or HCV (e.g. pathogenic organism of virus) in a liquid sample (please refer to claim 1).

For present claim 1, Wienhues et al. claim a method comprising the steps of a) incubating (1) sample, (2) a solid phase, (3) a first antigen for said antibody, wherein the first antigen has at least one marker group, and (4) a second antigen for said antibody, wherein the second antigen binds to the solid phase, under conditions to obtain an immune complex comprising a solid phase-bound second antigen to which is bound the antibody and to which is bound the first antigen; and b) detecting said antibody by direct or indirect detection of the marker group; and wherein at least one of said antigen is of formula (Ia) which is $(P\text{-})_nT(\text{-}L)_m$ or (Ib) which is $T(\text{-}P\text{-}L_m)_n$ wherein T is a carrier, P is a peptide comprising an epitope region and a spacer region wherein said epitope is reactive with the antibody and said spacer region comprises a peptide sequence of a length from 1 to 10 amino acids which is not reactive with the antibody, L is the marker group or a group which binds to the solid phase, - is a covalent coupling, n is 2-40 and m is 1-10 (please refer to claim 1).

For present claim 2, Wienhues et al. claim the first antigen comprises multiple epitope regions and the epitope regions being identical in amino acid sequence (please refer to claim 2).

For present claim 3, Wienhues et al. claim the second antigen comprises multiple epitope regions and the epitope regions being identical in amino acid sequence (please refer to claim 3). For present claim 4, Wienhues et al. claim the first antigen and the second antigen comprise multiple epitope regions and the epitope regions being identical in amino acid sequence (please refer to claim 4).

For present claim 5, Wienhues et al. claim that at least one marker group comprises a metal chelate marker group (please refer to claim 5).

For present claim 6, Wienhues et al. claim that indirect detection of the antibody comprises c) providing in step b) (of claim 1) the first antigen having the marker group comprising a hapten, and a binding partner for the hapten being labeled with a signal-generating group and d) detecting the antibody by detecting the signal-generating group (please refer to claim 6).

For present claim 7, Wienhues et al. claim the hapten is selected from the group consisting of a sterol, a bile acid, a sexual hormone, a corticoid, a cardenolide, a cardenolide-glycoside, a bufadienol, a steroid-sapogenine and a steroid alkaloid and wherein the specific binding partner comprises an antibody for the hapten (please refer to claim 7).

For present claim 9, Wienhues et al. claim at least one of the first antigen and the second antigen comprises a carrier to which the epitope regions are covalently coupled wherein the carrier is non-reactive with the antibody (please refer to claim 9).

For present claim 10, Wienhues et al. claim the carrier is a natural or synthetic peptide to polypeptide or a synthetic polysaccharide (please refer to claim 10).

For present claim 11, Wienhues et al. claim the carrier is selected form the group consisting of an albumin, an immunoglobulin, an immunoglobulin fragment, a β-galactosidase, a polylysine and a dextran (please refer to claim 11).

For present claim 12, Wienhues et al. claim that P is a synthetic peptide sequence of a length of from 6 to 50 amino acids (please refer to claim 12).

For present claim 14, Wienhues et al. claim that P is a recombinant polypeptide sequence of a length of up to 1000 amino acids wherein the polypeptide sequence comprises a single epitope region or a multiple of an epitope region (please refer to claim 14).

Therefore, the examined claims would have been obvious over the claims of U.S. Patent No. 6,613,530 B1 (Wienhues et al.).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS
April 13, 2006

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
	20060411

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply with requirements for Patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Any inquiry concerning this communication should be directed to Amber D. Steele, Art Unit 1639, whose telephone number is 571-272-5538.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 571-272-1600.

Applicant is given ONE MONTH from the date of this letter within which to comply with the Sequence Rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In NO case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Notice to Comply	Application No. 10/613,018	Applicant(s) W IENHUES ET AL.	
	Examiner Amber Steele	Art Unit 1639	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: "

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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